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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,602	07/30/2001	Sudhakar Kasina	690022.525C7	3183

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,602

Applicant(s)

KASINA ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-77 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 66-77 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- ☐ Interview Summary (PTO-413) Paper No(s). ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: .

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Response to Amendment

The preliminary amendments filed 7/30/2001 and 10/3/2001 have been entered. The continuing data has been inserted into the specification. Claims 1-65 have been canceled. New claims 66-77 have been added, are pending and have been examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 66-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 66, the recitation of "an annexin modified to provide an accessible sulphydryl group which is capable of participating in the complexation of a radionuclide" is indefinite. First, since annexins are not a specifically defined set of proteins (e.g., but is a class of proteins which differ depending on origin), thus, the term "modified" is unclear, since the starting annexin is not defined or the specific modifications made thereto. For example, the modifications made to annexin to have an "assessable sulphydryl" are confusing because most annexins have sulphydryl groups in cysteine residues, which would be "assessable" by some means. It is unclear what modifications have been made to the annexin or how the claimed annexin differs from a wild type annexin. Note, the claim does not include a hexose moiety or any additional amino acids (e.g., an extension), which are modifications. The specification defines a "modified annexin" on pages 10-11 of the specification, but this definition fails to provide an clear definition which provides for how the structure of the annexin in claim 66 would differ from various wild type annexins which contain a Cys residue, to provide a -SH group. Also, the term "accessible" renders this claim indefinite because it is unclear as to what means the -SH group is assessable. All -SH groups would be assessable by some means. Further, the recitation of "capable of" does not clarify this recitation, because any -SH group is "capable of" complexation with a radionuclide, even if this

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includes the use of ^{35}S , as well as others. Thus, the structure of the annexins that are being claimed cannot be determined. The dependent claims fall therewith.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 66-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Tait (WO 92/19279).

Tait discloses an annexin that contains one free sulphhydryl group, namely annexin V. This annexin is directly within the scope of claims 66-72, note: claim 72 defines the annexin (i.e., the claimed annexin), as annexin V. Tait specifically discloses radiolabeled annexin V, i.e., ^{125}I -annexin V, which is complexed with the radionuclide at a sulphhydryl group (-SH) of the third Cys residue (e.g., thus is a modified annexin, annexin V-N1), see examples I and XVII. This annexin contains a Gly residue and the -SH group of the Cys is within 10 amino acids from the N-terminus, see example XVII. The Gly and Cys residues would be within the scope of an extension, given various annexins can have different amino acid sequences (note: the term annexin is an unspecified protein, depending on its origin).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 66-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tait (WO 92/19279) in view of Reutelingsperger (US 5,627,036) or Theodore (US 5,578,287).

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Tait discloses an modified annexin V which is radiolabeled with ^{125}I at a -SH group, as set forth above.

Tait fails to teach that the modified annexins may be radiolabeled with other radionuclides, such as, $^{99\text{m}}\text{Tc}$.

Reutelingsperger discloses radiolabeled annexins that are radiolabeled with various radionuclides, as equivalents, include ^{125}I and $^{99\text{m}}\text{Tc}$, for use as diagnostic agents, see abstract and column 5, lines 45-51 and claim 12.

Theodore discloses conjugates comprising a targeting protein and a radionuclide that are useful for diagnostic and/or therapeutic methods, see column 2. Gustavson teaches that the targeting protein may be various targeting proteins, such an, annexins, see column 6, line 58. The chelating agents bind various radionuclides, (e.g., $^{99\text{m}}\text{Tc}$) see column 10, lines 24+ and teaches that $^{99\text{m}}\text{Tc}$ is especially preferred due to its low cost, convenient supply and favorable nuclear properties, see column 5, lines 48-62.

Thus, Reutelingsperger and Theodore teach that annexins may be labeled with $^{99\text{m}}\text{Tc}$ to provide a site-specific diagnostic and/or therapeutic agent.

It would have been obvious to one of ordinary skill in the art to modify the ^{125}I labeled annexins disclosed by Tait by substituting the ^{125}I for $^{99\text{m}}\text{Tc}$ because Reutelingsperger and Theodore both teach that $^{99\text{m}}\text{Tc}$ can be used as an equivalent radiolabel to ^{125}I for radiolabeling annexins, and because $^{99\text{m}}\text{Tc}$ is known to be a preferred radiolabel because of its low cost, convenient supply and favorable nuclear properties, as shown by Theodore.

Conclusion

No claims are allowed at this time.

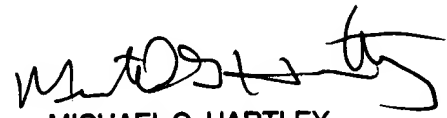
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628.

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The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

MH
September 26, 2002



MICHAEL G. HARTLEY
PRIMARY EXAMINER